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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,738	12/06/99	REYNOLDS	E 040268/0161

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HM22/1102

EXAMINER
LUKTON, D

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/380,738	Applicant(s) Reynolds
	Examiner David Lukton	Group Art Unit 1653

Responsive to communication(s) filed on Aug 16, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-38 is/are pending in the application

Of the above, claim(s) 1-6, 17-28, and 30-38 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 7-16 and 29 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Pursuant to a second preliminary amendment, claims 37 and 38 have been added. (These are joined with Group I). Claims 1-38 are now pending; this includes claims 29 and 30 presented pursuant to the article 34 amendment.

Applicants' election of Group II (claims 7-16, 29) is acknowledged, as is the elected species (the peptide Q-M-E-A-E-S-I-S-S-E-E-I-V-P-N-S-V-E-Q-K, wherein the serines are phosphorylated). The election of Group II is without traverse; however, it would be appropriate to revisit the issue of restriction after allowable subject matter has been identified, especially if applicants are willing to introduce the limitations of Group II into Group I.

\*

**An abstract is required,** and does not appear to have been submitted.

\*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may

be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

\*

Claims 4 and 10 contain underlining or brackets that are apparently intended to appear in the printed patent or are properly part of the claimed material. The brackets or underlining as used by the applicant are not intended to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii). Since underlining and brackets are normally used to indicate insertions and deletions, it is confusing to use the same in instances where the applicant desires to have the underlining and brackets appear in the published patent. If underlining or brackets are intended to appear as part of the printed patent claim, such claim should be presented in unamended form as a new claim, i.e., without the designation (amended), (twice amended), etc. as required by 37 CFR 1.121(a)(1)(B).

\*

Claims 7-16, 29 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, line 2, it appears that the term "phosphotopeptide" is misspelled.

Claim 9 recites the compound "HPO<sub>4</sub>". However, while the compounds H PO<sub>4</sub>, Na<sub>2</sub>HPO<sub>4</sub> and CaHPO<sub>4</sub> all exist, the same cannot be said for "HPO<sub>4</sub>".

Claim 12 (and claim 13) recites the abbreviations "PP" and "CP". These may be used, but only if accompanied by the appropriate definitions. For example, the following could be added to the end of claim 12:

*...wherein "PP" represents a phosphopeptide, and "CP" represents \_\_\_\_\_.*

Claim 29 is dependent on several non-elected claims. Moreover, it is a substantial duplicate of all previous claims. In addition, it is not clear what "hereinbefore" refers to.

\*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claims 7-9 are rejected under 35 U.S.C. §102(e or b) as being anticipated by Reynolds (USP 5,981,475) or Reynolds (*J. Dent. Res.* 74(6) 1272, 1995).

Each of the two references teaches a mixture of calcium phosphate and peptide comprising the sequence Ser(P)-Ser(P)-Ser(P)-Glu-Glu .

Thus, the claims are anticipated.

\*

Claims 7-11 are rejected under 35 U.S.C. §102(b) as being anticipated by Reynolds (*Proceedings of the Nutrition Society of Australia* **19**, 95-102, 1995) or Holt (*Biochem J.* **314**, 1035, 1996).

Each of Reynolds and Holt teaches at least one of the claimed sequences together with calcium phosphate.

Thus, the claims are anticipated.



\*

It is suggested that applicants delete the term "preventing" from line 1 of claim 25, and the phrase "or the like" from claim 27.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON  
PATENT EXAMINER  
GROUP 1600

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set by the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- 7. Other:

**Applicant Must Provide:**

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
- For CRF Submission Help, call (703) 308-4212
- For PatentIn software Program Support:
  - HELP DESK: (703) 739-8559, ext 508, M-F, 8 AM to 5 PM EST except holidays
  - Email: [PATIN21HELP@uspto.gov](mailto:PATIN21HELP@uspto.gov)
  - To purchase PatentIn software: (703) 306-2600

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